REMARKS

I. Status Summary

Claims 1-56 were filed with the subject application and have been examined by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Of these, claims 1-31 were cancelled in a preliminary amendment and claims 42-56 were cancelled as being drawn to unelected subject matter. Claim 57 was added with Amendment A, filed March 20, 2006. Claims 32-41 and 57 presently stand rejected.

The Patent Office has withdrawn claim 57 from consideration as allegedly being patentably distinct from SEQ ID NOs: 5 and 6, the subject of currently pending claims 32-41.

The Patent Office has objected to Amendment A filed March 20, 2006 as allegedly introducing new matter into the disclosure. Particularly, the Examiner contends that SEQ ID NO: 30 recited in claim 57 is not supported by the specification as filed.

Claims 32 and 39-41 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,977,247 to Fahnestock *et al.* (hereinafter referred to as "Fahnestock *et al.*").

Claims 33-38 have been objected to as improperly depending from rejected claim 32.

Reconsideration of the subject application in view of the following remarks is respectfully requested.

II. Response to the Patent Office Withdrawal of Claim 57

The Patent Office has withdrawn claim 57 from consideration as allegedly being patentably distinct from SEQ ID NOs: 5 and 6, the subject of currently pending claims 32-41. Particularly, the Patent Office asserts that the sequences contained in claim 57 are unrelated and patentably distinct such that an unduly burdensome search would

result.

After careful review of the instant withdrawal of claim 57 and the Patent Office's basis therefore, applicants respectfully traverse the withdrawal and submit the following remarks.

Claim 57 was added in Amendment A, filed March 20, 2006, in response to the previous Official Action dated September 21, 2005. Claim 57 is directed to amino acid sequences selected from SEQ ID NOs: 25, 26, 27, 28, 29 and 30. Upon review of SEQ ID NOs: 25, 26, 27, 28, 29 and 30, applicants respectfully submit that SEQ ID NOs: 25, 26, 27, 28, 29 and 30 differ from SEQ ID NO: 6 by at most one to three amino acid residues.

To elaborate, SEQ ID NO: 25 differs from SEQ ID NO: 6 by one amino acid. Particularly, SEQ ID NO: 25 represents an Alanine 27 to Xaa 27 mutation of SEQ ID NO: 6, where Xaa can be any naturally occurring amino acid except glutamine. The remaining amino acids of SEQ ID NO: 25 are identical to SEQ ID NO :6.

Similarly, SEQ ID NO: 26 differs from SEQ ID NO: 6 by two amino acids. Specifically, SEQ ID NO: 26 represents an Alanine 27 to Glutamine 27 and Lysine 28 to Xaa 28 double mutation of SEQ ID NO: 6, where Xaa can be any naturally occurring amino acid except lysine. The remaining amino acids of SEQ ID NO: 26 are identical to SEQ ID NO: 6.

Additionally, SEQ ID NO: 27 differs from SEQ ID NO: 6 by two amino acids. Specifically, SEQ ID NO: 27 represents an Alanine 27 to Glutamine 27 and Lysine 31 to Xaa 31 double mutation of SEQ ID NO: 6, where Xaa can be any naturally occurring amino acid except lysine. The remaining amino acids of SEQ ID NO: 27 are identical to SEQ ID NO: 6.

Further, SEQ ID NO: 28 differs from SEQ ID NO: 6 by two amino acids. Particularly, SEQ ID NO: 28 represents an Alanine 27 to Glutamine 27 and Asparagine 35 to Xaa 35 double mutation of SEQ ID NO: 6, where Xaa can be any naturally occurring amino acid except asparagine. The remaining amino acids of SEQ ID NO: 28 are identical to SEQ ID NO: 6.

Likewise, SEQ ID NO: 29 differs from SEQ ID NO: 6 by two amino acids. Particularly, SEQ ID NO: 29 represents an Alanine 27 to Glutamine 27 and Tryptophan 43 to Xaa 43 double mutation of SEQ ID NO: 6, where Xaa can be any naturally occurring amino acid except tryptophan. The remaining amino acids of SEQ ID NO: 29 are identical to SEQ ID NO: 6.

Further, SEQ ID NO: 30 differs from SEQ ID NO: 6 by three amino acids. Particularly, SEQ ID NO: 30 represents an Alanine 27 to Glutamine 27, Threonine 44 to Xaa 44, and Tyrosine 45 to Xaa 45 triple mutation of SEQ ID NO: 6, where Xaa can be any naturally occurring amino acid except threonine and tyrosine, respectively. The remaining amino acids of SEQ ID NO: 30 are identical to SEQ ID NO: 6.

Accordingly, applicants respectfully submit that upon review of SEQ ID NOs 25, 26, 27, 28, 29 and 30 and SEQ ID NO: 6, there are at most one to three amino acid mutations between the cited sequences and SEQ ID NO: 6. Accordingly, in view of the sequence similarities between SEQ ID NOs: 25, 26, 27, 28, 29 and 30 and SEQ ID NO:6, applicants respectfully submit that any search initiated by claim 57 (and SEQ ID NOs: 25, 26, 27, 28, 29 and 30) would not be unduly burdensome to the Patent Office in view of the noted sequence similarities.

Accordingly, applicants respectfully request that claim 57 be considered in the subject application.

III. Response to the Objection to Amendment A

The Patent Office has objected to Amendment A, filed March 20, 2006, as allegedly introducing new matter into the disclosure. Particularly, the Examiner contends that SEQ ID NO: 30 is not supported by the specification as filed. The Patent Office asserts that the support provided in Amendment A for SEQ ID NO: 30 is insufficient. Accordingly, the Patent Office asserts that the alleged new matter should be cancelled.

In response, applicants respectfully submit that contrary to the Patent Office's assertions, SEQ ID NO: 30 is indeed supported by the specification. Particularly,

applicants submit that SEQ ID NO: 30 represents an Alanine 44 to Xaa 44 and Alanine 45 to Xaa 45 double mutation of SEQ ID NO: 18, where Xaa can be any naturally occurring amino acid except threonine and tyrosine, respectively. Applicants submit that SEQ ID NO: 30 finds support in the specification at page 20, lines 1-7. Applicants wish to bring the Patent Office's attention to the specification amendment presented with Amendment A. Particularly, applicants submit that the specification at page 20, lines 1-7 was amended to correct for a typographical error (emphasis added):

> An alternative embodiment of a GB1 domain polypeptide of the present invention comprises mutations at a threonine 44 residue and at a tyrosine 45 residue of a native GB1 domain polypeptide. The mutation comprises a substitution of the threonine 44 residue and tyrosine 45 residue with any of the other 19 amino acids, as it is contemplated by the present inventors that any such substitution substantially abolishes Fc binding activity while maintaining Fab binding activity. Optionally, the substitution may comprise a comparatively non-polar amino acid residue, such as alanine, valine, leucine and isoleucine. A particularly contemplated example of such a GB1 polypeptide is disclosed in SEQ ID NO: 18.

Accordingly, applicants respectfully submit that support for SEQ ID NO: 30 can be found in the specification at page 20, lines 1-7, which suggests that the GB1 domain polypeptide can comprise a double mutation wherein threonine 44 and tyrosine 45 can be replaced with any other amino acid. Thus, applicants respectfully submit that no new matter has been added to the subject application.

Accordingly, applicants respectfully request that the objection to Amendment A be withdrawn at this time.

IV. Response to the 35 U.S.C. § 102(b) Rejection of Claims 32 and 39-41 in view of Fahnestock *et al.*

Claims 32 and 39-41 presently stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Fahnestock *et al.* Particularly, the Patent Office asserts that Fahnestock *et al.* teaches an isolated nucleic acid molecule encoding the B1

domain of Streptococcal Protein G polypeptide that binds a Fab fragment of an IgG but does not bind a Fc fragment of IgG.

After careful review of the instant rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Preliminarily, applicants note that it is well settled that for a cited reference to qualify as prior art under 35 U.S.C. § 102, each element of the claimed subject matter must be disclosed within the reference. "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Thus, applicants respectfully submit that for the cited reference to be an anticipation reference under 35 U.S.C. § 102, the reference must disclose each and every element of the claimed subject matter.

The Patent Office asserts that Fahnestock *et al.* teaches an isolated nucleic acid molecule encoding the B1 domain of Protein G polypeptide that binds a Fab fragment of an IgG but does not bind a Fc fragment of IgG that is comprised within a recombinant expression vector and a host cell. For support, the Patent Office asserts at page 5 of the Official Action that "Table 2 states that at pH5 Type 11 do not bind the Fc fragment, while at pH5 Type 11 does bind Fab fragment." However, applicants respectfully submit that the Patent Office is mischaracterizing the data contained in Table 2.

To elaborate, applicants submit that Fahnestock *et al.* discloses in Example XVI at columns 51-54 that Protein G variants were immobilized onto glass chromatography columns and connected to an HPLC system. The binding characteristics of the immobilized Protein G variants toward Fc, Fab, F(ab'), and IgG were then examined. After each column was equilibrated, Fc, Fab, F(ab') or IgG was applied. The column was then washed with PBS, eluted with 5 mM ammonium acetate pH 5, 0.5 M ammonium acetate pH 3, 1.0 M acetic acid, and equilibrated with PBS pH 7. The amount of Fc, Fab, F(ab'), or IgG that was eluted at each step was then quantitated.

Looking specifically at Table 2, applicants submit that Fc fragment was loaded

onto the Protein G variant Type 11 immobilized column. Table 2 indicates that 0.11 mg of Fc, or 8% of the total Fc loaded, was eluted in the initial flow through fractions. Accordingly, 92% of the Fc remained bound to Protein G variant Type 11. When 5 mM ammonium acetate pH 5 was then added to the column, none of the bound Fc was eluted. When 0.5 M ammonium acetate pH 3 was added to the column, 0.34 mg, or 25% of the total amount of Fc loaded, was eluted. When 1.0 M acetic acid was added to the column, 0.41 mg, or 31% of the total amount of Fc loaded, was eluted. When the column was equilibrated with PBS, the remaining 0.49 mg, or 36% of the total amount Fc loaded was eluted.

Hence, applicants respectfully submit that when viewed as a whole, Fahnestock *et al.* does not teach isolated GB1 polypeptide fragments that maintain binding activity for Fab fragments of an IgG, but do not bind Fc fragments. Rather, Fahnestock *et al.* appears to disclose Protein G variants that bind both Fc and Fab fragments of an IgG. In contrast, independent claim 32 of the subject application recites isolated nucleic acid molecules encoding a GB1 domain polypeptide that binds a Fab fragment of an IgG but does not bind a Fc fragment of an IgG.

Therefore, applicants respectfully submit that Fahnestock *et al.* does not support the instant 35 U.S.C. § 102(b) rejection of independent claim 32. Applicants further submit that claims 39-41, which depend from independent claim 32, have also been distinguished from Fahnestock *et al.*

Accordingly, applicants respectfully request that the instant 35 U.S.C. § 102(b) rejection of claims 32 and 39-41 be withdrawn at this time. A Notice of Allowance is also respectfully requested.

V. Response to the Objection to Claims 33-38

The Patent Office has objected to claims 33-38 as improperly depending from rejected claim 32.

In response, applicants respectfully submit that in view of the remarks presented hereinabove with regard to the 35 U.S.C. § 102(b) rejection of independent claim 32, the

rejection of claim 32 has been addressed. Accordingly, applicants respectfully submit that claims 33-38 no longer depend from a rejected base claim.

Thus, applicants respectfully request that the instant objection to claims 33-38 be withdrawn at this time.

VI. Conclusion

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and such action is earnestly solicited.

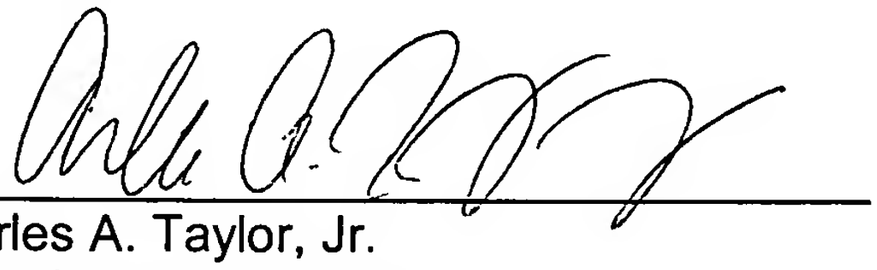
If any minor issues should remain outstanding after the Examiner has had an opportunity to study the Amendment and Remarks, it is respectfully requested that the Examiner telephone the undersigned attorney so that all such matters may be resolved and the application placed in condition for allowance without the necessity for another Action and/or Amendment.

DEPOSIT ACCOUNT

The Commissioner is authorized to charge any deficiencies or credit any overpayments associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,

JENKINS, WILSON, TAYLOR, & HUNT, P.A.

Date: December 28, 2006 By: 

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